

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

Antimicrobials Division (AD)

January 13, 2015

DP BARCODE: 422416

MRID:

SUBJECT: FANGIO

REG. NO.: 4822-ANA

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use [] OR End-use Product [X]

INGREDIENTS:

<u>PC Code(s)</u>	<u>CAS Number</u>	<u>Active Ingredient(s)</u>
128929	79-33-4	L-Lactic Acid

TEST LAB:

SUBMITTER: Lewis & Harrison

GUIDELINE: Group A and B Product Chemistry

ORGANIZATION: AD\PSB\CTT

REVIEWER: Lynette T. Umez-Eronini

APPROVED BY: Karen P. Hicks

APPROVED DATE: January 13, 2015

COMMENT: The product is for use on hard non-porous and non-food contact surfaces.

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MEMORANDUM

SUBJECT: Product Chemistry Review for EPA Reg. 4822-ANA
Product Name: FANGIO
DP Barcode: 422416

FROM: Lynette T. Umez-Eronini, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P) *Lynette T. Umez-Eronini*

THRU: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P) *Karen Hicks*

TO: Julia Chao PM #34/Jose Gayoso
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: S.C. Johnson & Son Inc.

CODE: A540 New Product; Non-Fast Track;

DATE DUE: February 2, 2015

PRODUCT FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
L-Lactic Acid	0.19
<u>Inert (Other) Ingredient(s):</u>	<u>99.81</u>
Total:	100.00

BACKGROUND:

The consultant, Lewis & Harrison on behalf of the registrant, S.C. Johnson & Sons Inc. has submitted an application for registration of a non-integrated end-use product called FANGIO. Product specific data for EPA Reg. No. 4822-593 would be used to support the registration for FANGIO. FANGIO is a cleaner, disinfectant and sanitizer for use on hard nonporous and non-food contact surfaces.

The product chemist reviewed the following documents:

1. Cover letter from the registrant to EPA, 6/17/2014.
2. Proposed Product Label, 6/17/2014.
3. Application for Pesticide Registration Form, 6/17/2014.
4. Formulators Exemption Statement, 6/17/2014.
5. Certification with Respect to Citation of Data, 6/17/2014.
6. Data Matrix Forms (Agency and Public versions), 6/17/2014, 3 pages each.
7. Basic and Alternate #1, #2, #3, and #4 Confidential Statements of Formula (CSFs), 6/17/2014.
8. Nine Certifications of the OPP Pilot Fragrance Notification Program for nine fragrances.

FINDINGS:

1. Nine fragrances listed on the CSFs are not on Agency's database. However, the fragrance suppliers for the said fragrances submitted a statement "For use when the fragrance supplier knows the fragrance identities and the registrant does not." The fragrance supplier certified that all the ingredients found in the fragrances to be used in EPA Reg. No 4822-XXX are listed on the Fragrance ingredient List and meet the other requirements of the Pilot Fragrance Notification Program. It is noted: XXX refers to the file symbol of the proposed new product.
2. The nominal concentration of the active ingredient on the Basic and Alternate #1, #2, #3, and #4 CSFs are consistent with the label.
3. The active ingredient source is EPA registered.
4. All certified limits meet EPA standard certified limits.
5. All ingredients in this formulation are approved for use in pesticide formulations.
6. Group A product chemistry data requirements applicable to end-use products have been met (see MRID 48859801 on Data Matrix and Table A below).
7. Group B product chemistry data requirements applicable to end-use products have been met (see MRID 48859802 on Data Matrix and Table B below).

CONCLUSION:

Product Science Branch of Antimicrobials Division finds the Basic and Alternate #1, #2, #3, and #4 CSFs, 6/17/2014 to be acceptable. Also, Group A and Group B Product Chemistry data requirements have been met.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system Yes [X] No []
- Are all TGAs used registered? Yes [] No [X]
- Integrated formulation system Yes [] No [X]
- If "ME-TOO," specify EPA Reg. No. of existing product:

b. Clearance of inerts for non-food or food use:

The product is cleared for food use under 40 CFR §180.940 and §180.950.

Yes [] No [X]

c. Physical state of product:

Liquid

d. The chemical IDs and analytical information (including that for the TGAs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes [X] No []

e. The NCs and CLs are acceptable.

Yes [X] No []

f. Active ingredient L-Lactic Acid

NC(%)
0.19200

LCL(%)
0.17200

UCL(%)
0.20800

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
Yes [] No [] Not applicable [X]
- Have all impurities of $\geq 0.1\%$ in the product been identified?
Yes [] No [] Not applicable [X]

II PRODUCT LABEL

a. The active ingredient statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes ☒ No ☐

b. The formula contains one of the following:

- | | | |
|--|------------------------------|--|
| • 10% or more of a petroleum distillate: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • 1.0% or more of methyl alcohol: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • sodium nitrite at any level: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • a toxic List 1 inert at any level: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • arsenic in any form: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this?

Yes ☐ No ☐ Not applicable ☒

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.

Yes ☐ No ☐ Not applicable ☒

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.

Yes ☒ No ☐

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).

Yes ☐ No ☐

Table A:
Product Chemistry (Series 830, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity ¹	A	Data Matrix (see 48859801)
830.1600 Description of Materials	A	Data Matrix (see 48859801)
830.1620 Production Process ²	NA	
830.1650 Formulation Process ³	A	Data Matrix (see 48859801)
830.1670 Formation of Impurities ⁴	NA	
830.1700 Preliminary Analysis ⁵	NA	
830.1750 Certified Limits ⁶	A	Data Matrix (see 48859801)
830.1800 Enforcement Analytical Method ⁷	A	Data Matrix (see 48859801)
830.1900 Submittal of Samples	[Samples are to be provided on a case by-case basis for end-use products.]	Chemistry Review for 4822-593, dated 8/22/2012

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

¹See Confidential Appendix A for additional information.

²For MP/EP products produced by an integrated formulation system.

³For products from a TGA or MP.

⁴May be waived unless actual/possible impurities are of toxicological concern.

⁵Five batch analysis required for products produced by an integrated formulation system.

⁶If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

⁷Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	NA		
830.6303 Physical State	A	Liquid	Data Matrix (see 48859802)
830.6304 Odor	N/A		
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NA		
830.6314 Oxidation/Reduction; Chemical Incompatibility	A	No significant oxidizing or reducing action or chemical incompatibility with KMnO_4 , $\text{NH}_4\text{H}_2\text{PO}_4$, turpentine or zinc.	Data Matrix (see 48859802)
830.6315 Flammability/Flame Extension	A	Flash point - $110.3 \pm 0.8^\circ\text{C}$	Data Matrix (see 48859802)
830.6316 Explodability	A	Product does not contain any explosive materials.	Data Matrix (see 48859802)
830.6317 Storage Stability	A	Average concentration of active ingredient remained within certified limits (0.158 to 0.194% wt/wt) after 12 months of storage at 25°C .	Data Matrix (see 49080601)
830.6319 Miscibility ¹	A	Product is not intended to be diluted with petroleum solvents.	Data Matrix
830.6320 Corrosion Characteristics	A	Product is not corrosive to packaging in PET containers for at least 12 months at 25°C .	Data Matrix (see 49080601)
830.6321 Dielectric Breakdown Voltage	A	Product is not intended for use around electrical outlets.	Data Matrix
830.7000 pH ²	A	4.02 ± 0.0 at $24.7 \pm 0.1^\circ\text{C}$	Data Matrix (see 48859802)
830.7050 UV/Visible Absorption	NA		

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.7100 Viscosity	A	0.95 + 0.071 cP and 0.98 ± 0.035 cP at 30 and 60 rpm, respectively at 20.1±0.0°C and 0.45 ± 0.071 cP and 0.50 ± 0.071 cP at 30 and 60 rpm, respectively at 40.0±0.1°C	Data Matrix (see 48859802)
830.7200 Melting Point/Melting Range	NA		
830.7220 Boiling Point/Boiling Range	NA		
830.7300 Density/Relative Density/Bulk Density	A	Relative Density - 1.0003 ± (0.0000 and Density - 0.9985 ± (0.0000) g/ml, at 20.0 ± (0.0) °C.	Data Matrix (see 48859802)
830.7370 Dissociation Constants in Water	NA		
830.7550/830.7560/830.7570 Partition Coefficient	NA		
830.7840/830.7860 Water Solubility	NA		
830.7950 Vapor Pressure	NA		

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* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

¹If product is an emulsifiable liquid

²If product is dispersible with water